US ERA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES September 20, 2007

NOTE TO RM 10 Ann Sibold

SUBJECT: CRP Protocol and Certification to Compliance with Child-Resistant Packaging Regulations EPA FILE NO: 65331-2, 3, 4, and 5 DP 341663, 341669, 341670, and 341671 Decision # 381219, 381220, 381221, and 381222

Please note that based on a September 18, 2007 telephone conversation with Tim Dotson at Merial they no longer wanting to test a pipette inside a blister card, which is inside a clear plastic hanging card. It is my understanding that Merial will be submitting a new protocol with a new package which involves the plastic card as being the CRP feature. Therefore I am not reviewing these protocols, but will await the new ones with the new sample package. I have verbally told the registrant that the protocols will not be reviewed.

To help Merial submit the proper type of protocol I have explained (on 8/6/07, 8/28/07 and 9/18/07) that both a child effectiveness test and a senior adult effectiveness test will have to be done in each size. The pipettes for EPA FILE NO: 65331-2 and 3 will be blue and for FILE NO: 65331-4 and 5 will be green. Therefore each color will have to be tested. However, I have concerns as to whether the child could see the pipette and possibly be attracted to certain pipette colors more than others. Therefore, I have proposed that Merial conduct testing on one color. Then, take the pipette size that has the most child failures and conduct one child test on that size in the other color. For instance, if the green pipettes are tested in 3 sizes then the one child test is all that would be done on the blue pipette. I am only requesting the child test as a change in pipette color should not effect the adult test. Merial should be reminded to come in with a CRP certification covering all 4 registration numbers.

Please officially advise the registrant that these protocols will not be reviewed and that we will await the new ones with the new sample package. If you have any questions please contact me at (703) 308-7368.

Rosalind L. Gross

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